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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/276,868	03/26/1999	MICHAEL SIMONS	BIS-043	2716

7590 01/19/2006

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EXAMINER	
KAM, CHIH MIN	
ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 01/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/276,868	SIMONS ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11 and 13-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11 and 13-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The Request for Continued Examination (RCE) filed on December 12, 2005 under 37 CFR 1.114 is acknowledged. An action on the RCE follows.

Status of the Claims

2. Claims 11 and 13-15 are pending.

Applicants' amendment filed December 12, 2005 is acknowledged, and applicant's response has been fully considered. Claims 11 and 15 have been amended, thus claims 11 and 13-15 are examined.

Maintained Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Previous rejection of claims 11 and 13-15 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is maintained. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 11 and 13-15 are directed to a PR-39 derived oligopeptide family whose members individually are operative and functional to cause a selective inhibition of proteasome-mediated degradation in-situ after introduction intracellularly to a viable cell, each member of said PR-39 derived oligopeptide family being a pharmacologically active oligopeptide which is not substantially greater than 11 amino acid residues or are less than 8 amino acid residues in length,

whose N-terminal amino acid residue sequence begins with Arg-Arg-Arg, which is an analog of the amino acid sequence of native PR-39 peptide, which selectively alters the proteolytic degradation activity of proteasomes, which is selectively interacts in-situ with at least the α7 subunit of proteasomes, and which is selectively inhibits proteolytic degradation mediated by the proteasomes against at least one peptide of IκBα and hypoxia-inducing factor-1α. While the specification indicates a member of PR-39 derived oligopeptide family is less than 39 amino acid residues, preferably is less than 20 residues (page 24, lines 12 –13), and further indicates the members "comprising" 15, 11 and 8 amino acid residues respectively in length (page 25, lines 1-4) represented as PR-15, PR-11 and PR-8 (the N-terminal fragments of PR-39; page 25), it does not disclose that active peptides are not substantially greater than 11 amino acid residues, or are less than 8 amino acid residues in length, nor describes any particular structure to function/activity relationship for the claimed species. The lack of description of the correlation of structure to function/activity and lack of representative species for the claimed peptide, one skilled in the art would not know how to identify a functional peptide. Thus, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

Response to Arguments

Applicants indicate that claims 11 and 15 have been amended to size-limited membership of PR-39 analog compositions which are not substantially greater than 11 amino acid residues or are less than 8 amino acid residues in length, and comprise a size-restricted family of PR-39 analog compositions which is severely limited in number, whose members are pharmacologically active, and two exemplary embodiments of this size-restricted family of oligopeptides are

identified and defined in dependent claims 13 and 14; that full information and detailed knowledge of the invention defined by currently amended independent claims 11 and 13-15 is to be found at pages 23-26 of the Specification; and empirical operative support is demonstrated by Experiment 6 (see page 45). Thus, that claimed invention is which is defined as the properly commensurate with that which is disclosed substantively equal to and by the written description of the Specification. Regarding the "new matter", applicant indicates the language of the claims did not depart from the totality of descriptive information and detailed knowledge presented by Specification text as a whole (pages 7-20 of the response).

Applicants' response has been considered, however, the argument is not found persuasive because the specification does not disclose active members of PR-39 derived oligopeptides are not substantially greater than 11 amino acid residues, or are less than 8 amino acid residues in length. Furthermore, the specification has not identified any PR-39 derived oligopeptide for the claimed species. The specification at pages 23-26 merely indicates an active member of PR-39 derived oligopeptide family having Arg-Arg-Arg at the N-terminus is less than 39 amino acid residues, preferably is less than 20 residues, and the members "comprising" 15, 11 and 8 amino acid residues respectively in length represented as PR-15, PR-11 and PR-8, and Experiment 6 (see page 45) only demonstrates PR11 (11 amino acid residues) has the activity of stimulating angiogenesis in vivo. Thus, due to the lack of description of the claimed species, a skilled artisan would not recognize applicants were in possession of the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 11, 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11, 13 and 14 are indefinite because of the use of the term "a pharmacologically active peptide which is not substantially greater than 11 amino acid residues in length". The term cited renders the claim indefinite, it is not clear what is the metes and bounds for the number of residues in the active peptide, e.g., is it 14, 13 or 12 amino acid residues? Claims 13 and 14 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

Conclusion

5. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner

CHIH-MIN KAM
PATENT EXAMINER

CMK

January 17, 2006